

III. Remarks

Claims 1-44, 56-61, 66, 67, 70, 71, 74-76, 81, 82, 84-96, 101-103, 106-110, and 112-122 were previously pending. Claims 93-96, 101-103, 106-110, 112, 113, 121, and 122 have been withdrawn from consideration. Claims 18, 19, and 21 have been canceled without prejudice to or disclaimer of the subject matter therein. No claims have been added.

Applicants appreciate the indication of allowance with respect to claims 114-119. Applicants also appreciate the indication that claims 88 and 89 would be allowable if rewritten in independent form. To that end, claim 88 has been rewritten in independent form. Claim 89 depends from and further limits claim 88. Accordingly, claims 88 and 89 are in condition for allowance.

Reconsideration of the presently pending claims is respectfully requested in light of the above amendments and the following remarks.

Rejections under 35 U.S.C. § 102

The Office Action indicated that **claims 1, 4-9, 13-15, 21, 24-29, 37, 56-61, 66, 67, 70, and 71** are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,401,269 to Buttner-Janz et al. ("the Buttner-Janz patent"). By this paper, claim 21 has been canceled. Claims 24-29 and 37 have been amended to depend from and further limit amended independent claim 22, which was not rejected under §102 over the Buttner-Janz patent.

The PTO provides in MPEP § 2131 that

“[t]o anticipate a claim, the reference must teach every element of the claim....”

Therefore, to sustain the rejection of the claims 1, 4-9, 13-15, 56-61, 66, 67, 70, and 71 the Buttner-Janz patent must teach all of the claimed elements of each claim.

With respect to amended independent claim 1, the Buttner-Janz patent at least fails to disclose an implant having all of the recited features of the claim, including “a deformable, resilient central body disposed between the inner surfaces of the shells comprising an outer surface, ... wherein an upper portion and a lower portion of the outer surface of the central body

are harder than an interior region of the central body disposed between the upper and lower portions.” In that regard, the Buttner-Janz patent discloses that the “prosthesis core 3 consists of a plastic with good sliding properties, especially high density polyethylene.” Col. 3, Lines 3-4. The prosthesis core 3 of the Buttner-Janz patent does not have an outer surface with upper and lower portions that are harder than an interior region of the central body disposed between the upper and lower portions of the outer surface, as required. Accordingly, the Buttner-Janz patent fails to disclose all of the recited elements of claim 1.

Claims 13-15 depend from and further limit claim 1. In that regard, the Buttner-Janz patent also fails to disclose the additional limitations regarding the outer surface of each rigid opposing shell as recited in claims 13-15. In particular, the cited portions of the Buttner-Janz patent fail to disclose, at least, for example “wherein the outer surface of each rigid opposing shell is coated with a biocompatible porous coating,” “wherein the porous coating comprises nonspherical sintered beads of a biocompatible metal or metal alloy,” and “wherein the rigid shell comprises a titanium alloy and wherein the porous coating comprises nonspherical sintered titanium beads,” as required. Accordingly, for these additional reasons the Buttner-Janz patent fails to disclose all of the claimed elements of claims 13-15. Therefore, Applicants respectfully request that the §102 rejection of claims 1 and 13-15 be withdrawn.

Similar to independent claim 1, amended independent claim 4 requires “a deformable, resilient central body disposed between the inner surfaces of the shells comprising an outer surface, ... wherein an upper portion and a lower portion of the outer surface of the central body are harder than an interior region of the central body disposed between the upper and lower portions.” As discussed above, the Buttner-Janz patent fails to disclose such limitations. Therefore, for at least the same reasons, the Buttner-Janz patent fails to disclose an implant with all of the recited limitations of claim 4. Claims 5-9 depend from and further limit claim 4. Therefore, Applicants respectfully request that the §102 rejection of claims 4-9 be withdrawn.

With respect to independent claim 56, the Buttner-Janz patent at least fails to disclose an implant having all of the recited features of the claim, including “wherein the central body has an upper and a lower contact surface, and wherein in the absence of a compressive load, an upper

shoulder is recessed into a portion of the perimeter of the upper contact surface and a lower shoulder is recessed into a portion of the perimeter of the lower contact surface.” (emphasis added). As shown below, Fig. 8B of the present application illustrates an exemplary embodiment of a central body having upper and lower shoulders 90 and 92 recessed into a portion of the perimeter of the respective contact surfaces.

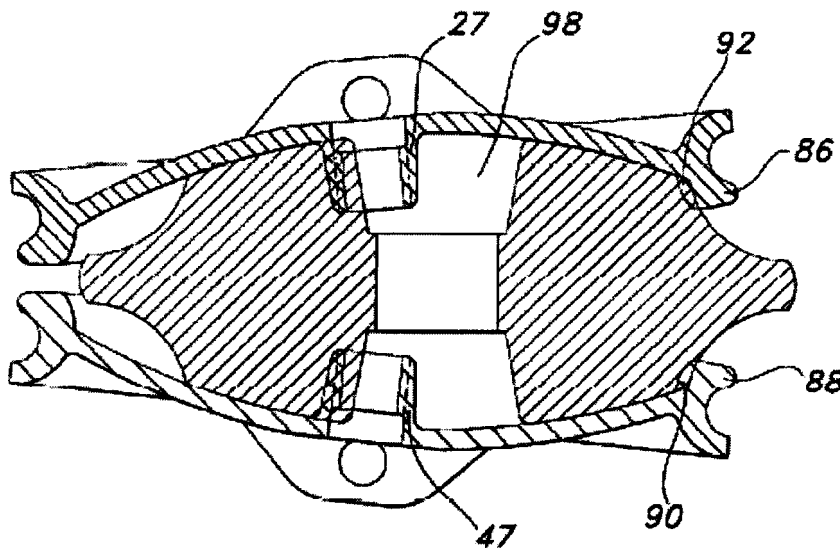


FIG 8B

The cited portions of the Buttner-Janz patent simply do not disclose having shoulders recessed in the upper and lower contact surfaces as recited. In that regard, the Office Action makes no mention of how or what portions of the Buttner-Janz patent may be interpreted to include such limitations. The provisions of 37 C.F.R. §1.104 specify that an Office Action must identify the relevant portions of a reference used to reject claims under §102. Specifically, §1.104 states, “[w]hen a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable.” The present Office Action does not reference a figure, a passage of text, or a reference numeral that would indicate which of the several embodiments in the Buttner-Janz patent the Examiner deems relevant to claim 56. Consequently, it is entirely unclear which parts of the Buttner-Janz patent are believed by the Examiner to anticipate claim 56. Claims 57 and 58 depend from and further

limit claim 56. Therefore, for at least these reasons Applicants respectfully request that the §102 rejection of claims 56-58 be withdrawn.

Similar to independent claim 56, independent claim 59 requires “wherein an upper shoulder extends around a portion of the perimeter of the upper contact surface and a lower shoulder extends around a portion of the perimeter of the lower contact surface and further wherein the upper shoulder defines a ledge indented into and around the perimeter of the upper contact surface of the central body.” As discussed above, the Buttner-Janz patent fails to disclose such limitations and the Office Action again does not reference a figure, a passage of text, or a reference numeral that would indicate which of the several embodiments in the Buttner-Janz patent the Examiner deems relevant to these limitations. Therefore, for at least the same reasons, the Buttner-Janz patent fails to disclose an implant with all of the recited limitations of claim 59. Claims 60 and 61 depend from and further limit claim 59. Therefore, Applicants respectfully request that the §102 rejection of claims 59-61 be withdrawn.

With respect to claims 66, 67, 70, and 71, each of these claims depends from and further limits independent claim 41. However, claim 41 is not rejected as being anticipated by the Buttner-Janz patent. In that regard, the Buttner-Janz patent at least does not disclose an elastic sheath as required by independent claim 41. Accordingly, the Buttner-Janz patent cannot disclose the recited elements of claims 66, 67, 70, and 71. Therefore, Applicants respectfully request that the §102 rejection of claims 66, 67, 70, and 71 be withdrawn.

The Office Action indicated that **claims 74-76** are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,002,576 to Fuhrmann et al. (“the Fuhrmann patent”). Therefore, to sustain the rejection of these claims the Fuhrmann patent must teach all of the claimed elements of each claim.

With respect to amended independent claim 74, the Fuhrmann patent at least fails to disclose an implant having all of the recited features of the claim, including “at least two opposing shells, a central body disposed between the two opposing shells, and at least one sealable opening in one of the at least two opposing shells for the introduction of a lubricant into the implant between the central body and the opposing shells after the implant has been

assembled.” Rather, the opening 21 in the cover plate 3” of the Fuhrmann patent “serves to fill the interior with viscoelastic material—or, together with a similar opening, as ventilation.” Col. 4, Lines 10-12. In the Fuhrmann patent, the viscoelastic material 2 fills a closed corrugated tube 1 to create the central spring body. Col. 2, Lines 52-67. In other words, the viscoelastic material 2 is part of the central body of the Fuhrmann device. Thus, the opening 21 is not for the “introduction of a lubricant into the implant between the central body and opposing shells,” as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form the central spring body. The viscoelastic material cannot be introduced between a central body and opposing shells because the viscoelastic material is the central body. Accordingly, for at least this reason the Fuhrmann patent fails to disclose all of the elements of claim 74. Therefore, Applicants respectfully request that the §102 rejection of claim 74 be withdrawn.

With respect to amended independent claim 75, the Fuhrmann patent at least fails to disclose an implant having all of the recited features of the claim, including “a central body and a lubricant encapsulated within the implant between the central body and a structure having at least one opening for the introduction of the lubricant into the structure, wherein the structure includes two shells and a sleeve extending between the shells, and the opening is included in at least one of the shells.” Again, the opening 21 in the cover plate 3” of the Fuhrmann patent “serves to fill the interior with viscoelastic material—or, together with a similar opening, as ventilation.” Col. 4, Lines 10-12. In the Fuhrmann patent, the viscoelastic material 2 fills a closed corrugated tube 1 to create a spring body that serves as the central body of the Fuhrmann device. Col. 2, Lines 52-67. Thus, the intervertebral disc of the Fuhrman patent does not include “a lubricant encapsulated within the implant between the central body and a structure ... wherein the structure includes two shells and a sleeve extending between the shells,” as required. Accordingly, the Fuhrmann patent fails to disclose all of the elements of claim 75.

Further, with respect to claim 76—which depends from and further limits claim 75—the Fuhrmann patent also fails to disclose “wherein both shells include openings.” The Fuhrmann patent discloses having an opening 21 in the upper plate 3”, but does not disclose having such an

opening in the lower plate 4. Accordingly, for at least this additional reason the Fuhrmann patent fails to disclose all of the recited elements of claim 76. Therefore, for at least these reasons Applicants respectfully request that the §102 rejection of claims 75 and 76 be withdrawn.

Rejections under 35 U.S.C. § 103

The Office Action indicated that **claims 2, 10-12, 18-20, 22, 23, 30-36, 81, 82, 84, 85, and 120** are rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of U.S. Patent No. 5,674,296 to Bryan et al. ("the Bryan patent"). By this paper, claims 18 and 19 have been canceled. Applicants respectfully traverse the rejection of claims 2, 10-12, 20, 22, 23, 30-36, 81, 82, 84, 85, and 120 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that the examiner has not factually supported a *prima facie* case of obviousness with respect to each of these claims in the present case.

Claims 2 and 10-12 depend from and further limit independent claim 1. As discussed above, the Buttner-Janz patent at least fails to disclose an implant having all of the recited features of claim 1, including "a deformable, resilient central body disposed between the inner surfaces of the shells comprising an outer surface, ... wherein an upper portion and a lower portion of the outer surface of the central body are harder than an interior region of the central body disposed between the upper and lower portions." Similarly, the Bryan patent fails to disclose all of the recited structural limitations. Accordingly, even when combined the Buttner-Janz patent and the Bryan patent fail to teach all of the claimed elements of claim 1 and, therefore, claims 2 and 10-12 as well. Therefore, Applicants respectfully request that the §103 rejection of claims 2 and 10-12 be withdrawn.

Similarly, claim 20 depends from and further limits claim 9, which depends from and further limits independent claim 4. As discussed above, the Buttner-Janz patent at least fails to

disclose an implant having all of the recited features of claim 4, including “a deformable, resilient central body disposed between the inner surfaces of the shells comprising an outer surface, ... wherein an upper portion and a lower portion of the outer surface of the central body are harder than an interior region of the central body disposed between the upper and lower portions.” Again, the Bryan patent fails to disclose all of the recited structural limitations. Accordingly, even when combined the Buttner-Janz patent and the Bryan patent fail to teach all of the claimed elements of claim 4 and, therefore, claims 9 and 20 as well. Therefore, Applicants respectfully request that the §103 rejection of claim 20 be withdrawn.

With respect to amended independent claim 22, even when combined the Buttner-Janz patent and the Bryan patent fail to disclose an implant having all of the recited limitations, including “a deformable, resilient central body ... comprising: a smooth convex upper surface ... and a smooth convex lower surface ... the upper and lower surfaces being harder than an interior region of the central body disposed between the upper and lower surfaces.” As discussed above, neither the Buttner-Janz patent nor the Bryan patent disclose all of the recited structural limitations, such as a deformable, resilient central body with upper and lower surfaces that are harder than an interior portion of the central body disposed between the upper and lower surfaces. Therefore, a *prima facie* case of obviousness has not been established with respect to claim 22. Claims 23 and 30-36 depend from and further limit claim 22. Accordingly, Applicants respectfully request that the §103 rejection of claims 22, 23, and 30-36 be withdrawn.

Further, claims 24-29 and 37, which previously depended from claim 21 and the Office Action indicated were rejected as being anticipated by the Buttner-Janz patent, now depend from and further limit claim 22. Thus, for at least the same reasons a *prima facie* case of obviousness has not been established with respect to claims 24-29 and 37 as well.

With respect to independent claim 81, even when combined the Buttner-Janz patent and the Bryan patent fail to disclose an implant having all of the recited limitations, including “two spaced shells ... wherein at least one shell has a first edge that includes a radial stop extending generally axially from a portion thereof ... wherein the radial stop is adapted to contact a shoulder formed in the central body when translational, flexural, or extensional forces are applied to the

implant.” The Office Action implies that the Buttner-Janz patent discloses all of the limitations of claim 81, except for the limitation “wherein the first edge has an outer circumferential groove.” However, the Buttner-Janz patent does not disclose a shell having a first edge that includes an axially extending radial stop, as required. Rather, the Buttner-Janz patent discloses a core 3 having a collar 7 for cooperating with a rim 8 of the prosthesis plates 1, 2. Col. 3, Lines 14-16. A core with a collar is not a shell having a first edge including an axially extending radial stop. Similarly, the Bryan patent does not disclose a shell structure having the recited structural limitations. Accordingly, even when combined the Buttner-Janz patent and the Bryan patent fail to disclose an implant having all of the recited limitations of claim 81 and, therefore, a *prima facie* case of obviousness has not been established. Claims 82, 84, and 120 depend from and further limit claim 81. Therefore, Applicants respectfully request that the §103 rejection of claims 81, 82, 84, and 120 be withdrawn.

With respect to independent claim 85, even when combined the Buttner-Janz patent and the Bryan patent fail to disclose an implant having all of the recited limitations, including “two shells ... wherein at least one shell has an edge that includes a radial stop extending generally axially from a portion thereof, at least one shell has an edge that includes a tab extending generally axially from a portion thereof, and the radial stop and the tab are on the same shell and they extend from the shell in opposite directions and wherein the radial stop is adapted to contact a shoulder formed in the central body when translational, flexural, or extensional forces are applied to the implant.” As discussed above with respect to claim 81, neither the Buttner-Janz patent nor the Bryan patent disclose an implant having a shell with an axially extending radial stop for contacting a shoulder of the central body, as required. Accordingly, even when combined the Buttner-Janz patent and the Bryan patent fail to disclose an implant having all of the recited limitations of claim 85 and, therefore, a *prima facie* case of obviousness has not been established. Applicants respectfully request that the §103 rejection of claim 85 be withdrawn.

The Office Action indicated that **claims 3, 16, 17, 38-44, 86, 87, and 90-92** are rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of the Bryan patent in view of the Fuhrmann patent. Applicants respectfully traverse this rejection on the

grounds that these references are defective in establishing a *prima facie* case of obviousness.

Claim 3 depends from and further limits independent claim 1. As discussed above, even when combined the Buttner-Janz patent and the Bryan patent at least fail to disclose an implant having all of the recited features of claim 1, including "a deformable, resilient central body disposed between the inner surfaces of the shells comprising an outer surface, ... wherein the outer surface of the central body is harder than an interior region of the central body." Similarly, the Fuhrmann patent does not disclose such a central body either. Accordingly, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to teach all of the claimed elements of claim 1 and, therefore, claim 3 as well. Therefore, Applicants respectfully request that the §103 rejection of claim 3 be withdrawn.

With respect to independent claim 16, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to disclose an implant having all of the recited limitations, including "wherein at least one of the rigid opposing shells further comprises a closable passage between its outer surface and its inner surface ... wherein the closable passage is configured in a manner that permits the introduction of a lubricant into the implant between the central body and the opposing shells." As discussed above with respect to claims 74 and 75, the opening 21 of the Fuhrmann disc is not for the "introduction of a lubricant into the implant between the central body and opposing shells," as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form a central spring body. As such, the viscoelastic material cannot be introduced between a central body and opposing shells because the viscoelastic material is the central body.

Further, there is no reason for combining the opening 21 of the Fuhrmann disc with the devices of the Buttner-Janz patent and the Bryan patent other than hindsight. Recently, the Supreme Court ruled that the "teaching, suggestion, or motivation (TSM) test" still applies, but should be used in a more "expansive and flexible" manner. *KSR Int'l. Co. v. Teleflex Inc.*, slip opinion at 14-15 (2007). The Court stated that

"A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” Id. at 14-15, emphasis added.

In the present case, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Bryan patent. The Office Action states that “it would have been obvious ... to modify the device of Buttner-Janz/Bryan et al., as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant. However, the devices of the Butter-Janz and Bryan patents include substantially solid core or central pieces. The central pieces of the Buttner-Janz and Bryan patents are not formed by filling a tube with viscoelastic material as in the Fuhrmann patent. Thus, one would not modify the devices of the Buttner-Janz and Bryan patents to fill the implant with a viscoelastic material to create a central body. Further, there is no indication why one would combine ventilation with the Buttner-Janz and Bryan devices. Accordingly, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Bryan patent. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 16. Claim 17 depends from and further limits claim 16. Therefore, Applicants respectfully request that the §103 rejection of claims 16 and 17 be withdrawn.

With respect to independent claim 41, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to disclose an implant having all of the recited limitations, including

“an upper and a lower rigid, opposed biocompatible concavo-convex shell, each comprising: ... a first ridge circumscribing the contact area of the inner concave surface and extending axially

toward the opposing shell; ... a deformable, resilient central body disposed between the inner, smooth concave surfaces of the upper and lower shells, comprising: ... a shoulder circumscribing each of the smooth convex upper and lower surfaces and adapted to contact the first ridge of the adjacent shell and limit the relative motion of the shell with respect to the central body; a laterally extending equatorial ridge disposed between the first ridge of the upper concavo-convex shell and the first ridge of the lower concavo-convex shell.”

In particular, even when combined the cited references do not disclose a central body having a shoulder circumscribing upper and lower surfaces for contacting the ridge of a shell—the ridge circumscribing a contact area of the inner surface of the shell—and a laterally extending equatorial ridge disposed between the ridge of the upper shell and the ridge of the lower shell, as required. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 41. Claims 42-44 depend from and further limit claim 41. Therefore, Applicants respectfully request that the §103 rejection of claims 41-44 be withdrawn.

With respect to independent claim 86, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to disclose an implant having all of the recited limitations, including “two shells interconnected by a sleeve to form a cavity therein, and a central body having at least one indentation therein positioned within the cavity, wherein ... at least one of the shells includes an opening to allow introduction of a lubricant into the cavity.” As discussed above with respect to claims 16, 74, and 75, the opening 21 of the Fuhrmann disc is not configured for the introduction of a lubricant into cavity having a central body positioned therein. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form a central spring body. As such, the viscoelastic material cannot be introduced into a cavity having a central body positioned therein because the viscoelastic material is the central body. Further, as discussed above with respect to claim 16, there is no reason for combining the opening 21 of the Fuhrmann disc with the devices of the Buttner-Janz patent and the Bryan patent other than hindsight. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 86. Claim 87 depends from and further limits claim 86. Therefore, Applicants respectfully request that the §103 rejection of

claims 86 and 87 be withdrawn.

With respect to claim 90, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to disclose a method having all of the recited steps, including “[a] method of introducing the lubricant into the implant of claim 86 comprising slightly compressing the implant to remove excess air, and injecting the lubricant into the opening.” In particular, none of the references discloses “slightly compressing the implant to remove excess air, and injecting the lubricant into the opening,” as recited. Further, the Office Action makes no mention of how or what portions of the references may be interpreted to include such limitations. The provisions of 37 C.F.R. §1.104 specify that an Office Action must identify the relevant portions of a reference used to reject claims under §103. Specifically, §1.104 states, “[w]hen a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable.” The present Office Action does not reference a figure, a passage of text, or a reference numeral that would indicate which of the several embodiments of each of the references the Examiner deems to disclose the recited elements. Therefore, for at least these reasons a *prima facie* case of obviousness has not been established. Applicants respectfully request that the §103 rejection of claim 90 be withdrawn.

Similarly, with respect to independent claim 91 even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to disclose a method having all of the recited steps, including “[a] method of introducing the lubricant into the implant of claim 87 comprising: (1) sealing one of the openings, (2) slightly compressing the implant to remove excess air, (3) injecting the lubricant into the unsealed opening, and (4) sealing the second opening.” As noted above with respect to claim 90, none of the references discloses “slightly compressing the implant to remove excess air” and injecting the lubricant into the opening, as recited. Further, none of the references discloses having an implant with an opening in both shells, as required. The Fuhrmann patent discloses having an opening 21 in the upper plate 3”, but does not disclose having such an opening in the lower plate 4. The Buttner-Janz and Bryan patents do not disclose having openings. Thus, even when combined the references cannot teach “sealing one of the openings,” “injecting lubricant into the unsealed opening,” and “sealing the

second opening.” Accordingly, for at least these reasons the references fail to disclose all of the claimed elements of claim 91. Therefore, for at least these reasons a *prima facie* case of obviousness has not been established with respect to claim 91. Claim 92 depends from and further limits claim 91. Accordingly, Applicants respectfully request that the §103 rejection of claims 91 and 92 be withdrawn.

IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims are in condition for allowance. Should the Examiner deem that an interview with Applicants’ undersigned attorney would expedite consideration, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

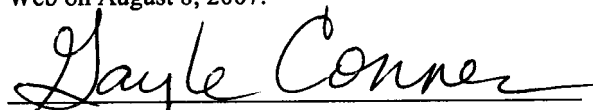


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Gayle Conner